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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/534,930

12/22/2005

Marcus Patrick Carey

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EXAMINER

PATEL, TARLA R

ART UNIT

PAPER NUMBER

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/534,930	Applicant(s) CAREY, MARCUS PATRICK	
	Examiner TARLA R. PATEL	Art Unit 3772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) 16-33 and 35-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 and 34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 May 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/13/05, 1/5/06, 6/19/08 and 8/6/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I and Species (c) in the reply filed on 6/26/08 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Applicant elected claims 1-15, 33 and 34, with claim 34 believed to be generic to all Species of Group I, to that the examiner respectfully disagrees. Claim 34 require a splint includes two longitudinally extending side arms, however Group I require either mesh or splint, further the Species a and b require various shape flexible synthetic mesh including plurality of pores and Species d require inflated intra-vaginal splint. Therefore, claim 34 is directed to Group I Species c that is elected by applicant.

2. Claims 16-33 and 35-38 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Groups and Species. Further, after review claim 33 is also withdrawn from further consideration pursuant to 37 CFR 1.142 (b) as being drawn to a nonelected Species. With respect to claim 33, it recites the limitations requiring a plurality of open pores bounded by strands are without open interstices, therefore it is also directed to the non-elected species (b).

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on 5/13/05, 1/5/06, 6/19/08 and 8/6/08. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Specification

4. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

5. The abstract of the disclosure is objected to because abstract must be on separate sheet. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1-15 and 34 are rejected under 35 U.S.C. 102(e) as being anticipated by Rosenblatt et al. (6,981,983).

Rosenblatt et al. discloses a method for repairing a vaginal wall which has been damaged by one or more prolapsed pelvic organs (abstract and column 3 lines 41-67)

Art Unit: 3772

method comprising mobilizing the vaginal epithelium off the underlying fascia of at least a portion of the damaged vaginal wall (column 13 lines 14-60), positioning a prosthetic material over the exposed fascia (see figure 25D), re-fixing the vaginal epithelium over the prosthetic material and the fascia and thereafter (column 1 lines 51-63 and column 19 line 45-column 21 line 28) locating an intra-vaginal splint into the vagina (see figure 25D).

With respect to claims 2-3, Rosenblatt et al. inherently discloses the vaginal wall being repaired is the anterior vaginal wall and the vaginal epithelium is mobilized off the underlying fascia by incision and lateral dissection through the arcus tendineous fascia pelvis and continued towards the sacrospinous ligaments on both sides and into the paravaginal space on each side of the anterior vaginal wall (column 1 lines 51-63 and column 19 line 45-column 21 line 28).

With respect to claim 4, Rosenblatt et al. inherently discloses the prosthetic (600) is a synthetic mesh having laterally extending arms (604 and 602) on both sides and the mesh is positioned over the exposed fascia of the anterior vaginal wall with each lateral arm (604 and 602) of the mesh placed into tunnels extending from the anterior vaginal wall dissection into the paravaginal spaces (see figure 25D).

With respect to claim 5, Rosenblatt et al. the vaginal wall being repaired is the posterior wall of the vagina and the vaginal epithelium is mobilized off the underlying fascia by incision and dissection laterally to the levator ani muscles on each side and in the upper part of the vagina in a lateral and cranial direction through the rectal pillars on both

Art Unit: 3772

sides towards the sacrospinous ligaments on each side of the vaginal wall (see figure 25D) and (column 1 lines 51-63 and column 19 line 45-column 21 line 28).

With respect to claim 6, Rosenblatt et al. inherently discloses the prosthetic (600) is a synthetic mesh having upwardly extending arms (630) on both sides and the mesh is positioned over the exposed fascia of the posterior vaginal wall with each upwardly extending arm (630) of the mesh placed into tunnels extending from the posterior vaginal wall dissection to the respective sacrospinous ligament (see figure 25D and column 1 lines 51-63).

With respect to claims 7, 9 and 13, Rosenblatt et al. discloses prosthetic material/intra-vaginal splint once positioned over the exposed fascia of the vaginal wall being repaired is thereafter attached to the underlying fascia by sutures (column 1 lines 51-63 and column 13 lines 25-26).

With respect to claim 8, Rosenblatt et al. discloses the fascia of the damaged vaginal wall is plicated after the vaginal epithelium has been mobilized but prior to the positioning of a prosthetic material over the exposed fascia (column 1 lines 51-63 and column 19 line 45-column 21 line 28).

With respect to claims 10-11 and 14-15, Rosenblatt et al. discloses the intra-vaginal splint remains located within the range for a period of at least three weeks and between 4 to 6 weeks following location within the vagina (as disclosed in column 3 lines 31-36 discloses that the system to hold intact soft tissue structures together would provide a repair of sufficient duration is interpreted as having splint remaining located in the

Art Unit: 3772

vagina for a period of at least 3 weeks and between 4 to 6 weeks to fully repair the vagina).

With respect to claim 34, Rosenblatt et al. discloses the intra-vaginal splint (600) includes two longitudinally extending side arms (630) both having first and second ends (as shown in figure 25C side arm having top end as first end and bottom end as second end), side arms being connected at their respective first ends by a first connecting member (604) and at their respective second ends by a second connecting member (602), wherein first and second connecting members are of different lengths (see figure 25C).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TARLA R. PATEL whose telephone number is (571)272-3143. The examiner can normally be reached on M-T 6-3.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on 571-272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3772

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Tarla R Patel/
Examiner, Art Unit 3772

/Patricia Bianco/
Supervisory Patent Examiner, Art Unit 3772